Stuber, Robyn

From: Denton, Debra
Sent: Thursday, May 28, 2015 9:55 AM
To: Stuber, Robyn; Smith, DavidW
Subject: FW: Withdrawal of Approval of the SWRCB Alternative Test Procedure for the Two-concentration Test Design for NPDES
Attachments: Memo response to ATP rejection letter from USEPA 5-12-15.doc; ATP Request to Dr Eugenia McNaughton February 2014.docx; ATP approval withdrawal letter 2112015.docx; Feb 11 2015 EPA letter to SWRCB withdrawal final.pdf; may 15th 2015 clean water act method update comments.pdf

Hi

just - fyi

PEACE = Purposefully Express Appreciation and Compassion for Everyone Debra

Disclaimer: This message was written with voice activated software. It may contain errors. Some of them might be interesting. Observe the context and the meaning will, hopefully, be obvious.

Debra L. Denton, PhD
Environmental Scientist
US EPA Region 9
Water Quality Assessment Section (WTR-2-1) c/o SWRCB
1001 I Street
Sacramento, CA 95814
phone (916) 341-5520

_____

From: Breuer, Rich@Waterboards [rich.breuer@waterboards.ca.gov]
Sent: Thursday, May 21, 2015 2:10 PM
To: McNaughton, Eugenia; Denton, Debra
Subject: FW: Withdrawal of Approval of the SWRCB Alternative Test Procedure for the Two-concentration Test Design for NPDES

Dear Eugenia and Debra

I wanted to provide you with the materials we have sent to our program managers in response to the ATP two concentration test approval withdrawal.
I have also attached our comments to USEPA on the "Clean Water Act Methods Update Rule for the Analysis of the Effluent" dated May 15th 2015.

Sincerely

Rich Breuer

Rich Breuer
Assistant Director, Office of Information Management and Analysis State Water Resources Control Board

1001 I Street, Room 16-03
Sacramento, California 95814
Desk phone: (916) 341-5220 Cell: (916) 956-9604 Mailing address: P.O. Box 100 Sacramento, CA 95812-0100

http://www.waterboards.ca.gov/water_issues/programs/swamp/

From: Breuer, Rich@Waterboards
Sent: Thursday, May 21, 2015 2:03 PM
To: WB-DIT-DMC
Cc: Messina, Diana@Waterboards; Morris, Cris@Waterboards; Macedo, Julie@Waterboards; Okamoto, Mayumi@Waterboards; Rasmussen, Rik@Waterboards; Anderson-Abbs, Beverley@Waterboards; Bennett, Jarma@Waterboards; Bucknam, Stephanie@Waterboards; Burres, Erick@Waterboards; Davey, Meirve@Waterboards; Heinz, Candice@Waterboards; Maag, Eric@Waterboards; Marshack, Jon@Waterboards; Marshall, Toni@Waterboards; Morris, Melissa@Waterboards; Ogg, Brian@Waterboards; Pathak, Sahil@Waterboards; Petta, Marc@Waterboards; Pham, Kimberly@Waterboards; Salisbury, Jennifer@Waterboards; Spears, Renee@Waterboards; Tadesse, Dawit@Waterboards; Tang, Michelle@Waterboards; Tappel, Mary@Waterboards; Thao, Mike@Waterboards; Van Dyke, Marisa@Waterboards; Webber, Lori@Waterboards; Yang, Calvin@Waterboards; Zarghami, Rassam@Waterboards
Subject: Withdrawal of Approval of the SWRCB Alternative Test Procedure for the Two-concentration Test Design for NPDES

Dear Assistant Executive Officers, Assistant Directors, and Managers,

The purpose of the attached memo is to inform you of the February 11, 2015 notice of withdrawal of the United States Environmental Protection Agency's (USEPA) approval of the State Water Resources Control Board's (State Water Board) Alternative Test Procedure (ATP) request. USEPA had approved the request to use the two-concentration test design when using the Test of Significant Toxicity (TST). This memo includes our interpretation of the withdrawal and its ramifications for the Water Boards' permitting process requirements.

The attached documents are relevant where toxicity testing is part of your regulatory programs. Please distribute to the appropriate managers within your organization.

Sincerely,

Rich Breuer

Rich Breuer
Assistant Director, Office of Information Management and Analysis State Water Resources Control Board
1001 I Street, Room 16-03
Sacramento, California 95814
Desk phone: (916) 341-5220 Cell: (916) 956-9604 Mailing address: P.O. Box 100 Sacramento, CA 95812-0100

http://www.waterboards.ca.gov/water_issues/programs/swamp/

ALIFORNIA
Water Boards

EDMUND G. BROWN JR.
GOVERNOR

MATTHEW RODRIQUEZ
SECRETARY FOR
ENVIRONMENTAL PROTECTION

State Water Resources Control Board

TO: Water Board Managers and Staff

FROM: Rich Breuer, Assistant Deputy Director

OFFICE OF INFORMATION MANAGEMENT AND ANALYSIS

DATE: May 12th, 2015

SUBJECT: Withdrawal of Approval of the SWRCB Alternative Test Procedure for the Two-Concentration Test Design for NPDES Effluent Testing when using the Test of Significant Toxicity

The purpose of this memo is to inform you of the February 11, 2015 notice of withdrawal of the United States Environmental Protection Agency's (USEPA) approval of the State Water Resources Control Board's (State Water Board) Alternative Test Procedure (ATP) request. USEPA had approved the request to use the two-concentration test design when using the Test of Significant Toxicity (TST). This memo includes our interpretation of the withdrawal and its ramifications for the Water Boards' permitting process requirements.

History and Timeline

In a letter dated February 12, 2014, the SWRCB Quality Assurance Officer, Renee Spears, submitted an ATP request to USEPA Region 9 for the statewide use of a two-concentration toxicity test design when using the Test of Significant Toxicity (TST) approach (Attachment 1). This two-concentration test design is composed of a single effluent concentration and a control concentration.

The TST statistical analysis only requires the biological responses from the two-concentration test design. Currently the multiple-concentration test design (a minimum of five effluent concentrations compared to a control concentration) is required under Code of Federal Regulations, title 40, section 136.3. The two-concentration test design is more cost effective when using the TST since, at a minimum, the number of concentrations necessary is reduced by four (including all the replicates).

As stated in the February 12th letter, State Water Board staff is developing a toxicity amendment to the Water Quality Control Plan for Enclosed Bays and Estuaries of California that will standardize the regulation of aquatic toxicity for all non-oceanic surface waters. U.S. EPA's TST approach is an essential component of this draft toxicity amendment as it forms the basis for utilizing numeric water quality objectives and acts as the primary means of determining compliance with the proposed effluent limitations. It provides a definitive value of whether a sample is toxic versus an interpreted (and debatable) value as determined by the NOEC and IC_{25} approaches.

USEPA approved the ATP request on March 17th 2014 (Attachment 2). In June 2014, the approval was challenged in court on procedural grounds under the Administrative Procedures Act by the Southern California

Alliance of Publicly Owned Treatment Works (SCAP) and the Central Valley Clean Water Association (CVCWA). After nine months of legal interaction, the USEPA withdrew the approval and notified us in a memo dated February 11th, 2015 (Attachment 3[1]).

Reasons for Withdrawal

The three reasons for withdrawal, as described in the rejection letter, are clearly identified as procedural errors as part of the ATP submittal at the state level, as well as the USEPA's approval and procedural processes.
It is important to note that USEPA's rescission of its approval of the ATP is not based on the substantive TST statistical analysis or the scientific validity of a two-concentration test design. There is no reference to the scientific validity of either the two-concentration test design or the TST, which is significant.
The rejection letter also states that currently there is a proposed rulemaking to change the language in the ATP regulations at Code of Federal Regulations, title 40, section 136. Once we are notified by USEPA that the changes are in effect, we will resubmit the ATP request in the proper format.

What Does this Mean for the Water Boards?

There is confusion regarding what test design can or cannot be required or used in the permitting process. The following sections help provide clarification when determining what is required and what is discretionary.

Test Design

Based on the withdrawal of the ATP approval, the following chart (Table 1) shows where you must require the multiple-concentration test design and where you can use the two-concentration test design in non-marine permits. In all other toxicity testing situations, you may specify the two-concentration test design which includes storm water, Non-point source programs, and the Surface Water Ambient Monitoring Program (SWAMP) studies.

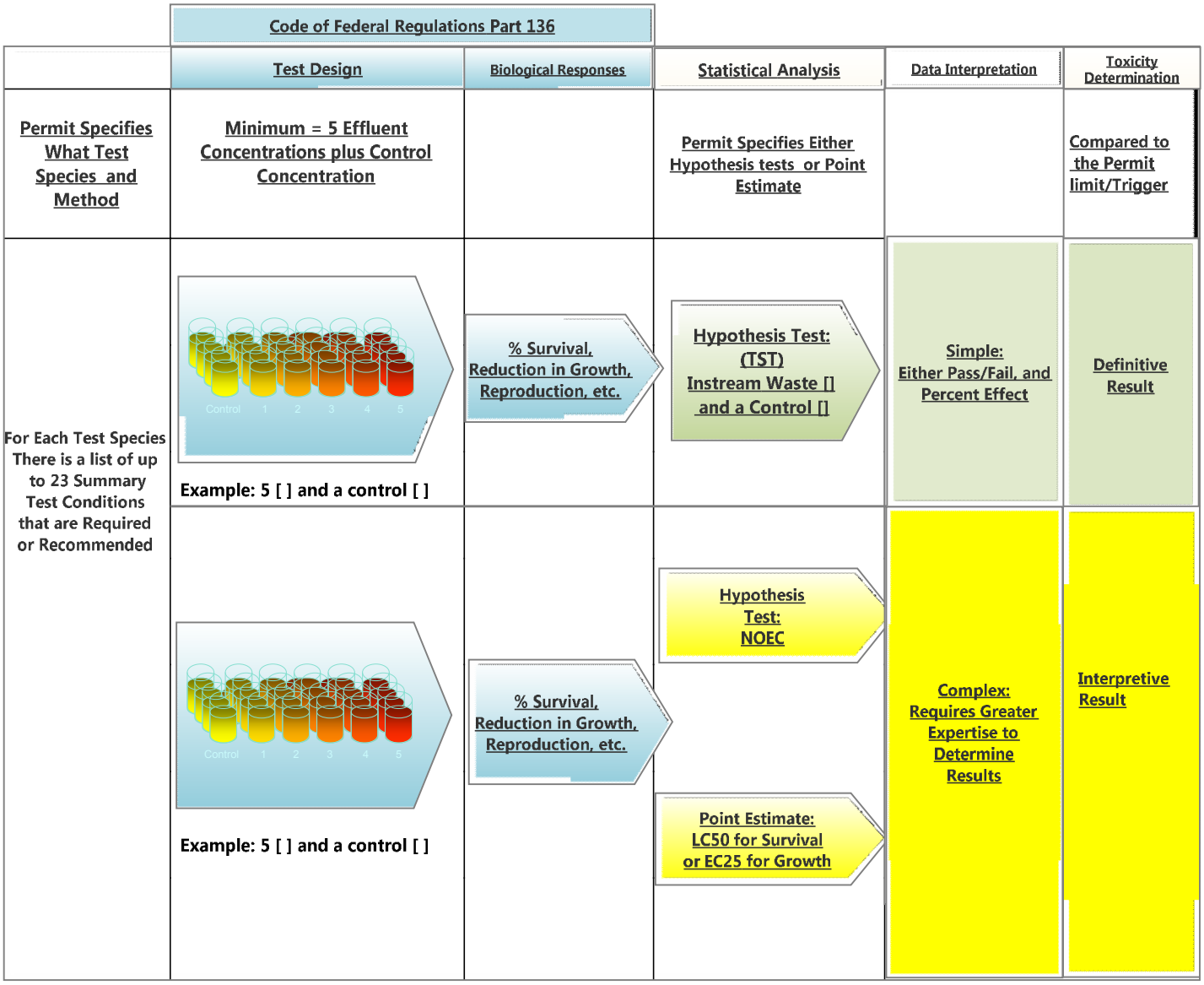
Table 1. Test Design Requirements for NPDES Permits

Method	Must conduct a minimum of Five concentrations and a control	May conduct with only one concentration and a control
Chronic Freshwater Test species (USEPA 2002a[2])	Effluent	Storm Water Receiving Water
Acute Freshwater or Marine test species (USEPA. 2002b[2])	Effluent	Storm Water Receiving Water
Chronic East Coast Marine Test species (USEPA 2002c[2])	Effluent	Storm Water Receiving Water

[1] The USEPA withdrawal memo erroneously refers to the two-concentration test design as "two effluent concentrations plus a control." The actual design uses one effluent concentration plus a control (which, by definition, is an effluent concentration of zero.)

[2]Note: According to USEPA test methods (USEPA 2002a, 2002b, 2002c), under the "Summary of Test Conditions and Test Acceptability Criteria for Daphnid, *Ceriodaphnia dubia*, survival and reproduction Toxicity Tests with Effluents and Receiving Waters" --- there is testing condition listed as "test concentrations":
"Effluents: Five and a control (required minimum)
Receiving Waters: 100% receiving water (or minimum of five) and a control (recommended)"

Figure 1. Toxicity Testing and Analysis Pathways for NPDES Permits Requiring the Multiple-Concentration Test Design



What is Required and What is Discretionary Within the Permit?

For those permits specified which are required to use the multiple-concentration test design, **Figure 1.** illustrates the following:

1. The permit specifies what test species and method to be used
2. The multiple-concentration test design requirement is required under Code of Federal Regulations, title 40, section 136.3
3. The biological responses are also incorporated by reference in Code of Federal Regulations, title 40, section 136.3
4. The permit specifies the statistical analysis, such as:
    a. A hypothesis test using the TST
    b. A hypothesis test using the NOEC
    c. A point estimate test using LC50 or EC25

Can I Still Require the use of the TST in NPDES Permits?

Yes. The benefits of requiring the TST in new or amended permits include improving the statistical power of the toxicity test, and it is simpler to use than either traditional hypothesis test methods or point estimates. The calculations are straightforward and provide a clear pass/fail result. As stated above, the TST analysis only needs the biological responses from the two-concentration test design. Our request for approval of the use of the two-concentration test design for TST analyses was for USEPA to review and approve the most cost effective test design needed to achieve complete results using the TST. With the withdrawal of the two-concentration test design approval, an NPDES permit can still require the TST for statistical analyses, but only the biological responses from the permitted Instream Waste Concentration (IWC) and the control (effluent concentration of zero) are utilized. However, even with only two of the five concentration biological responses being used, cost savings in the form of time and effort are still realized for the statistical analysis and data interpretation carried out by the permittee, lab, and permit manager.

Additional Information

For additional information please contact Ms. Renee Spears, SWRCB QA Officer at (916) 341-5583, or Renee.Spears@waterboards.ca.gov.

References:

USEPA. 2002a. Short-term methods for estimating the chronic toxicity of effluents and receiving waters to freshwater organisms. Fourth Edition. Office of Water, Washington, DC. EPA/821/R-02/013.

USEPA. 2002b. Methods for measuring the acute toxicity of effluents and receiving waters to freshwater and marine organisms. Fifth Edition. Office of Water, Washington, DC. EPA/821/R-02/012.

USEPA. 2002c. Short-term methods for estimating the chronic toxicity of effluents and receiving waters to marine and estuarine organisms. Third Edition. Office of Water, Washington, DC. EPA/821/R-02/014.

Attachments:

1. ATP Request to Dr. Eugenia McNaughton February 12, 2014
2. ATP Approval Letter from EPA R9 March 17, 2014
3. ATP Approval Withdrawal Letter February 11, 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

February 11, 2015

Renee Spears
Senior Environmental Scientist Specialist-QA Officer
Office of Information Management & Analysis
State Water Resources Control Board
1001 I Street, 16-39D- Sacramento, CA 95814
P.O. Box 100- Sacramento, CA 95812

Dear Ms. Spears:

This letter addresses the EPA Region 9 Quality Assurance Office's March 17, 2014 approval of the State of California's request to use an Alternate Test Procedure (ATP), authorizing the use of two concentrations in lieu of the five concentrations plus a control specified in the WET test methods, when using the Test of Significant Toxicity (TST) statistical approach. EPA is withdrawing the approval of the Limited Use ATP, effective immediately, for a number of reasons. Please note that at this time, California's February 12, 2014 ATP request is no longer pending before EPA and should the State wish to pursue such an ATP, a new ATP application would be required.

As you may know, the March 17, 2014 Limited Use ATP approval was challenged in the U.S. Eastern District Court of California in June 2014 by the Southern California Alliance of Publicly Owned Treatment Works (SCAP) and Central Valley Clean Water Association (CVCWA). As a result of the litigation, EPA has become aware of issues related to the State of California's February 12, 2014 request as well as EPA Region 9's approval. First, we note that the State's request cited 40 C.F.R. § 136.4, which describes the process for *nationwide* ATP approvals, rather than 40 C.F.R. § 136.5 for a Limited Use ATP. While we continue to believe this was a simple error, we acknowledge that it has created uncertainty and confusion among the regulated community.

Second, there is currently pending a proposed rulemaking to revise the ATP regulations at 40 C.F.R. Part 136. Please see http://water.epa.gov/scitech/methods/cwa/mur2015.cfm. The EPA Administrator signed a proposed rule on February 5, 2015, relevant portions of which are attached. One element of that rulemaking is a proposal to correct an inadvertent error in the 40 C.F.R. § 136.5 regulatory language regarding Limited Use ATPs. In revising 40 C.F.R. § 136.5 in 2012, EPA had inadvertently included the phrase "or permitting authority" after each instance that the phrase "Regional Alternate Test Procedure Coordinator" or "Regional ATP Coordinator" appears in Section 136.5. The effect of this inadvertent inclusion was to authorize State

permitting authorities to approve ATPs. This was not EPA's intention, and EPA has now proposed to delete the phrase "or permitting authority" from Section 136.5. It is EPA's position that the inadvertent error is not implicated in its approval decision here, but plaintiffs have raised arguments regarding the phrase "permitting authority" in Section 136.5. To the extent this error has created uncertainty in regards to the appropriateness of the March 17, 2014 ATP approval, EPA believes it is appropriate to withdraw that approval. However, withdrawal of the approval does not affect any aspect of the regulations at 40 C.F.R. Part 136 but concerns only the State's February 12, 2014 ATP request.

Third, plaintiffs have raised concerns with respect to the administrative record for the ATP approval. In light of some of the issues raised by plaintiffs, EPA has concluded that it is appropriate to withdraw its ATP approval. If you have any questions regarding this action, please contact me at (415) 972-3411.

Sincerely,

Eugenia McNaughton

Eugenia McNaughton, Ph.D.
Manager, Quality Assurance Office

Cc: Rich Breuer

J. Clarifications/Corrections to ATP Procedures in 40 CFR 136.4, 136.5 and Allowed Modifications in 136.6

40 CFR 136.4 and 136.5 describe EPA procedures for obtaining approval to use an alternate test procedures either on a national basis, or for limited use by dischargers or facilities specified in the approval. In the 2012 Method Update Rule, EPA made several clarifying changes to the language of these sections. At the same time, however, in many places in 40 CFR 136.4 and 136.5 where the phrase "Regional Alternate Test Procedures Coordinator" or "Regional ATP Coordinator" appears, EPA inadvertently also inserted the phrase "or permitting authority" following the phrase. This error resulted from the use of the "search and replace" function on the computer. The effect of the change was to inadvertently authorize *State* permitting authorities to approve ATPs for limited use within the State. EPA never intended this result as is demonstrated by two facts. First, in its proposal for the 2012 Update, EPA did not propose to authorize State NPDES permitting authorities to approve limited use ATPs. Second, the rule states that the approval may be restricted to specific dischargers or facilities, or to all dischargers or facilities "specified in the approval *for the Region*." (emphasis added). This language evidences EPA's intent that the Region – not the state – would be authorized to issue any such limited use ATP approval. Finally, as further evidence of EPA's intent, in several places, the text of the rule makes more sense if read to authorize only the Regional ATP Coordinator, and not the State permitting authority, to approve limited use ATPs. For example, 40 CFR 136.5(d)(1) provides as follows:

> "After a review of the application by the Alternate Test Procedure Regional ATP Coordinator or permitting authority, the Regional ATP Coordinator or permitting

authority notifies the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure…."

As currently written, if the State is acting on a request for approval, the regulation would require the State to inform itself of its own action in approving or rejecting the ATP, a somewhat superfluous requirement.

Consequently, EPA proposes to delete all instances of "or permitting authority" from 40 CFR 136.4 and 136.5 to correct this error and revise the rule text to its original intent. Based on this revision, EPA and EPA alone would have the authority to approve limited use ATPs.

EPA also proposes changes to 40 CFR 136.4 and 136.5 to clarify the process for nationwide approval and the Regional ATP Coordinator's role in limited use ATP approvals. These changes do not significantly change the process, the intent is to make wording simpler and clearer.

Finally, EPA proposes to add language to 40 CFR 136.6(b)(1) to clarify that if a method user is uncertain whether or not a modification is allowed under 40 CFR 136.6, the user should contact either its Director or EPA Regional ATP Coordinator.

K. Changes to Appendix B to 40 CFR part 136 - Definition and Procedure for the Determination of the MDL

EPA proposes revisions to the procedure for determination of the MDL primarily to address laboratory blank contamination and to better account for intra-laboratory variability. EPA's consideration of revisions to the MDL procedure for this rulemaking is specific to these revisions, and other changes to the procedure are outside the scope of this action. The proposed changes originated from The National Environmental Laboratory Accreditation Conference

5. Section 136.4 is amended by revising paragraphs (a) introductory text, (b), and (c) to read as follows:

§ 136.4 Application for and approval of alternate test procedures for nationwide use.

(a) A written application for review of an alternate test procedure (alternate method) for nationwide use may be made by letter via email or by hard copy in triplicate to the National Alternate Test Procedure (ATP) Program Coordinator (National Coordinator), Office of Science and Technology (4303T), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Any application for an ATP under this paragraph (a) shall:

* * * * *

(b) The National Coordinator may request additional information and analyses from the applicant in order to evaluate whether the alternate test procedure satisfies the applicable requirements of this part.

(c) Approval for nationwide use.

(1) After a review of the application and any additional analyses requested from the applicant, the National Coordinator will notify the applicant, in writing, of whether the National Coordinator will recommend approval or disapproval of the alternate test procedure for nationwide use in CWA programs. If the application is not recommended for approval, the National Coordinator may specify what additional information might lead to a reconsideration of the application and notify the Regional Alternate Test Procedure Coordinators of the disapproval recommendation. Based on the National Coordinator's recommended disapproval of a proposed alternate test procedure and an assessment of any current approvals for limited uses for the

unapproved method, the Regional ATP Coordinator may decide to withdraw approval of the method for limited use in the Region.

(2) Where the National Coordinator has recommended approval of an applicant's request for nationwide use of an alternate test procedure, the National Coordinator will notify the applicant. The National Coordinator will also notify the Regional ATP Coordinators that they may consider approval of this alternate test procedure for limited use in their Regions based on the information and data provided in the application until the alternate test procedure is approved by publication in a final rule in the Federal Register.

(3) EPA will propose to amend 40 CFR part 136 to include the alternate test procedure in §136.3. EPA shall make available for review all the factual bases for its proposal, including the method, any performance data submitted by the applicant and any available EPA analysis of those data.

(4) Following public comment, EPA shall publish in the FEDERAL REGISTER a final decision on whether to amend 40 CFR part 136 to include the alternate test procedure as an approved analytical method for nationwide use.

(5) Whenever the National Coordinator has recommended approval of an applicant's ATP request for nationwide use, any person may request an approval of the method for limited use under §136.5 from the EPA Region.

6. Section 136.5 is amended by revising paragraphs (a), (b), (c), and (d) to read as follows:

§136.5 Approval of alternate test procedures for limited use.

(a) Any person may request the Regional ATP Coordinator to approve the use of an alternate test procedure in the Region.

(b) When the request for the use of an alternate test procedure concerns use in a State with an NPDES permit program approved pursuant to section 402 of the Act, the requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority). The Director will forward the application to the Regional ATP Coordinator with a recommendation for or against approval.

(c) Any application for approval of an alternate test procedure for limited use may be made by letter via email or by hard copy. The application shall include the following:

(1) Provide the name and address of the applicant and the applicable ID number of the existing or pending permit(s) and issuing agency for which use of the alternate test procedure is requested, and the discharge serial number.

* * * * *

(d) Approval for limited use. (1) The Regional ATP Coordinator will review the application and notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. The approval may be restricted to use only with respect to a specific discharge or facility (and its laboratory) or, at the discretion of the Regional ATP Coordinator, to all dischargers or facilities (and their associated laboratories) specified in the approval for the Region. If the application is not approved, the Regional ATP Coordinator shall specify what additional information might lead to a reconsideration of the application.

(2) The Regional ATP Coordinator will forward a copy of every approval and rejection notification to the National Alternate Test Procedure Coordinator.

7. In Section §136.6:

Clean Water Act Methods Update Rule for the Analysis of Effluent

List of Subjects in 40 CFR part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Test procedures, Water pollution control.

Dated:

FEB 05 2015

Gina McCarthy, Administrator.

February 12, 2014

Eugenia McNaughton, Ph.D., Chief
Quality Assurance Office
U.S. Environmental Protection Agency, Region 9
75 Hawthorne Street
San Francisco, CA 94105

Dear Dr. McNaughton:

Pursuant to Code of Federal Regulations, title 40, section 136.4, the State Water Resources Control Board (State Water Board) is submitting this application for US EPA Region 9 review and approval of the statewide Alternate Test Procedure use of a two-concentration test design when using the Test of Significant Toxicity (TST) hypothesis testing approach.

State Water Board staff is developing an amendment to the Water Quality Control Plan for Enclosed Bays and Estuaries of California that will standardize the regulation of aquatic toxicity for all non-oceanic surface waters. The United States Environmental Protection Agency's (US EPA) TST hypothesis testing approach (US EPA 2010) is an essential component of this proposed toxicity amendment as it forms the basis for the numeric water quality objectives and acts as the primary means of determining compliance with the effluent limitations.

Toxicity tests are vital tools used to measure the aggregate effects of pollutants, detect unknown toxicants, and assess their bioavailability in a more effective manner than that of pollutant-specific tests and bioassessments. Test methods, developed for both freshwater and marine organisms, are divided between acute and chronic endpoints. Acute toxicity tests measure lethality, while chronic toxicity tests focus on sub-lethal effects, such as reductions in growth and reproduction. Currently, toxicity tests are used to determine compliance with the narrative objectives for toxicity established in the Regional Water Quality Control Plans (Basin Plans). Section 4 of the Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (State Implementation Policy or SIP) establishes minimum chronic toxicity requirements for implementing these narrative water quality objectives for toxicity. However, discrepancies persist among the toxicity requirements included in National Pollutant Discharge Elimination System (NPDES) permits and Waste Discharge Requirements (WDR). The draft toxicity amendment seeks to create a uniform regulatory framework to address these inconsistencies through the required use of the TST for all NPDES wastewater and point source WDR dischargers in California.

Use of the TST does not alter the test procedures used to produce the biological endpoints of US EPA's toxicity test methods (e.g. organism age, food, temperature, exposure length); it merely alters the minimum number of test concentrations required for toxicity testing.

The benefits of the TST approach have been lauded by numerous academicians. The five peer reviewers selected in a blind fashion for US EPA's peer review process agreed that the TST's bioequivalence approach is sound and that the results of TST analyses are reasonable and defensible. The State Water Board also initiated a peer review focusing on the use of the TST approach in the draft Policy for Toxicity Assessment and Control (the previous iteration of the toxicity amendment). The two researchers, Dr. Gerald A. Le Blanc and Dr. Michael C. Newman, concluded that the TST is a "…major advance from the currently compromised No Observed Effects Concentration (NOEC) approach," and "…is statistically sound, reduces burden associated with the assays, and, by structuring the assay around a hypothesis of significant toxicity, provides incentive for precision in assay performance." In addition, four individual articles examining the TST approach have been published in two respected, peer-reviewed toxicological journals (Denton et al. 2011, Diamond et al. 2011, Zheng et al. 2012, Diamond et al. 2013), while the State Water Board published a report (State Water Board 2011-please see attachment) comparatively analyzing the results of over 3,000 toxicity tests using both the TST and traditional hypothesis approaches. Although this "test drive" analysis showed that the results of the NOEC and TST are generally the same, it is important to note that the TST correctly identified truly non-toxic samples more often than the NOEC did. Moreover, the NOEC failed to identify more truly toxic samples than the TST approach.

The TST approach is currently being used to implement Tribal and Territory NPDES permits issued by US EPA Region 9, as well as the US EPA Region 9 offshore oil and gas general permit (No. CAG280000). The State Water Board has included provisions requiring the use of the TST approach in the Caltrans general permit for storm water discharges (Order No. 2012-0011-DWQ), the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064), the San Diego Regional Water Quality Control Board's general permit for discharges from boatyards and boat maintenance and repair facilities (Order No. R9-2013-0026), and the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064). The TST approach has also been incorporated into several NPDES permits in Hawaii.

The State Water Board is confident that the use of the TST will strengthen toxicity regulation throughout California. Apart from improving the statistical power of toxicity test methods, the TST is simpler to use than either traditional hypothesis test methods or point estimates. In addition, the two-concentration test design will reduce the cost of toxicity monitoring for most wastewater dischargers in California. For these, and the other reasons discussed previously in this letter, the State Water Board requests that US EPA Region 9 review and approve the use of a two-concentration test design for TST-based analyses of the whole effluent toxicity testing methods promulgated in Code of Federal Regulations, title 40, section 136.3.

Sincerely,

Renee Spears
Quality Assurance Officer

cc: (via e-mail)

Jonathan Bishop, Chief Deputy Director
State Water Resources Control Board

Victoria Whitney, Deputy Director
Division of Water Quality
State Water Resources Control Board

Phillip Crader, Assistant Deputy Director
Division of Water Quality
State Water Resources Control Board

Rich Breuer, Assistant Deputy Director
Office of Information Management
State Water Resources Control Board

Rik Rasmussen, Section Chief
TMDL Section
State Water Resources Control Board

Brian Ogg, Environmental Scientist
Inland Planning Standards and
Implementation Unit
State Water Resources Control Board

References:

Denton DL, Diamond JM, Zheng L. 2011. Test of Significant Toxicity: A Statistical Application for Assessing Whether an Effluent or Site Water is Truly Toxic. *Environmental Toxicology and Chemistry.* DOI: 10.1002/etc.493.
http://onlinelibrary.wiley.com/doi/10.1002/etc.493/full

Diamond JM, Denton DL, Roberts Jr. JW, Zheng L. 2013. Evaluation of the Test of Significant Toxicity for Determining the Toxicity of Effluents and Ambient Water Samples. *Environmental Toxicology and Chemistry.* DOI: 10.1002/etc.2166.
http://onlinelibrary.wiley.com/doi/10.1002/etc.2166/full

Diamond J, Denton D, Anderson B, Phillips B. 2011. It is time for changes in the analysis of whole effluent toxicity data. *Integrated Environmental Assessment and Management.* DOI: 10.1002/ieam.278.
http://onlinelibrary.wiley.com/doi/10.1002/ieam.278/full

Regional Water Quality Control Board, San Diego Region. 2013. General Waste Discharge Requirements for Discharges from Boatyards and Boat Maintenance and Repair Facilities Adjacent to Surface Waters within the San Diego Region. Order No. R9-2013-0026.
http://www.waterboards.ca.gov/sandiego/board_decisions/adopted_orders/2013/R9-2013-0026.pdf

Regional Water Quality Control Board, San Diego Region. 2013. Waste Discharge Requirements for the United States Department of the Navy Naval Base, San Diego Complex, San Diego County. Order No. R9-2013-0064.
http://www.waterboards.ca.gov/sandiego/board_decisions/adopted_orders/2013/R9-2013-0064.pdf

State Water Resources Control Board. 2011. *Effluent, Stormwater, and Ambient Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST).*
http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/final_testdrive.pdf

State Water Resources Control Board. 2012a. Policy for Toxicity Assessment and Control, Public Review Draft.
http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/draft_tox_policy_0612.pdf

State Water Resources Control Board. 2012b. National Pollutant Discharge Elimination System (NPDES) Statewide Storm Water Permit Waste Discharge Requirements (WDRS) for State of California Department of Transportation. Order No. 2012-0011-DWQ.
http://www.swrcb.ca.gov/board_decisions/adopted_orders/water_quality/2012/wqo2012_0011_dwq.pdf

State Water Resources Control Board peer review:

Gerald A. LeBlanc, PhD
http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/gerald_leblanc_review.pdf

Michael C. Newman, PhD
http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/michael_newman_review.pdf

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CALIFORNIA
Water Boards

EDMUND G. BROWN JR.
GOVERNOR

MATTHEW RODRIQUEZ
SECRETARY FOR
ENVIRONMENTAL PROTECTION

State Water Resources Control Board

May 14, 2015

Water Docket, Environmental Protection Agency
Attention: Docket ID # EPA-HQ-OW-2014-0797
Mail code: 4203M, 1200 Pennsylvania Ave. NW.
Washington, DC 20460

State Water Resources Control Board (State Water Board) staff would like to thank the United States Environmental Protection Agency (U.S. EPA) for the opportunity to comment on the "Clean Water Act Methods Update Rule for the Analysis of Effluent." This letter will focus exclusively on the proposed revisions to *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms, Fifth Edition, Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, Fourth Edition,* and *Methods for Measuring the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms, Third Edition* (collectively: toxicity method manuals).

State Water Board staff supports the clarifying edits and updates proposed for the toxicity method manuals. In addition, State Water Board staff is requesting a revision to the five-concentration minimum required for all toxicity test methods in order to comport with the U.S. EPA's newest statistical approach, the Test of Significant Toxicity (TST), as it statistically compares only the instream waste concentration and a control.

The benefits of the TST approach have been lauded by numerous academicians. The five peer reviewers selected in a blind fashion for U.S. EPA's peer review process agreed that the TST's bioequivalence approach is sound, and that the results of TST analyses are reasonable and defensible. The State Water Board also initiated a peer review focusing on the use of the TST approach in the draft *Policy for Toxicity Assessment and Control*. The two researchers, Dr. Gerald A. Le Blanc and Dr. Michael C. Newman, concluded that the TST is a "...major advance from the currently compromised No Observed Effects Concentration (NOEC) approach," and "...is statistically sound, reduces burden associated with the assays, and, by structuring the assay around a hypothesis of significant toxicity, provides incentive for precision in assay performance." In addition, four individual articles examining the TST approach have been published in two respected, peer-reviewed toxicological journals (Denton et al. 2011, Diamond et al. 2011, Zheng et al. 2012, Diamond et al. 2013), while the State Water Board published a report comparatively analyzing the results of over 3,000 toxicity tests using both the TST and "traditional" hypothesis approaches (State Water Board, 2011). Although this "Test Drive" analysis showed that the results of the NOEC and TST are generally the same, it is important to note that the TST correctly identified truly non-toxic samples more often than the NOEC did. Moreover, the NOEC failed to identify more truly toxic samples than the TST approach.

The TST approach is currently being used to implement Tribal and Territory NPDES permits issued by U.S. EPA Region 9, as well as the U.S. EPA Region 9 offshore oil and gas general permit (No. CAG280000). The State Water Board has included provisions requiring the use of the TST approach in the Caltrans general permit for storm water discharges (Order No. 2012-0011-DWQ), the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064), the San Diego Regional Water Quality Control Board's general permit for discharges from boatyards and boat maintenance and repair facilities (Order No. R9-2013-0026), and the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064). The TST approach has also been incorporated into several NPDES permits in Hawaii.

It is worth noting that the toxicity method manuals clearly state that the statistical approaches featured therein are merely recommendations. As such, requiring the use of five concentrations for TST analyses is inherently contradictory. Therefore, State Water Board staff is suggesting the addition of the following language (in red) to the "Test Concentration" requirement in the toxicity method manuals' "Summary of Test Conditions" tables:

Effluents:	5 and a control (required minimum for LOEC and NOEC endpoints, and point estimates) 1 and a control (required minimum for TST)
Receiving Water:	100% receiving water (or minimum of 5) and a control (recommended)

In addition to the inclusion of the *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document* in the "Cited References" section, State Water Board staff believes it would also be helpful to update the sections of the toxicity method manuals that discuss "pass/fail" tests with the following language (in red):

With the exception of the Test of Significant Toxicity (TST), ~~U~~use of pass/fail tests consisting of a single effluent concentration (e.g., the receiving water concentration or RWC) and a control is not recommended. If the NPDES permit has a whole effluent toxicity limit for acute toxicity at the RWC, it is prudent to use that permit limit as the midpoint of a series of five effluent concentrations for the LOEC and NOEC endpoints, and for point estimates. This will ensure that there is sufficient information on the dose-response relationship. For example, the effluent concentrations utilized in a test may be: (1) 100% effluent, (2) (RWC + 100)/2, (3) RWC, (4) RWC/2, and (5) RWC/4. More specifically, if the RWC = 50%, appropriate effluent concentrations may be 100%, 75%, 50%, 25%, and 12.5%. Guidance for the TST approach is provided in the National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (USEPA 2010).

These minor revisions will eliminate the extremely wasteful practice of utilizing five test concentrations for TST analyses while greatly improving regulatory interpretation.

Sincerely,

Greg Gearheart, Director
Office of Information Management and Analysis

Rich Breuer, Assistant Deputy Director
Office of Information Management and Analysis

Rik Rasmussen, Chief
Total Maximum Daily Load Section

Zane Poulson, Chief
Inland Planning Standards and Implementation Unit

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http://www.ncbi.nlm.nih.gov/pubmed/23172744

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

February 11, 2015

Renee Spea rs
Senior Environmental Scientist Specialist-QA Officer
Office of Information Management & Analysis
State Water Resources Control Board
1001 I Street, 16-39D- Sacramento, CA 95814
P.O. Box 100- Sacramento, CA 95812

Dear Ms. Spears:

This letter addresses the EPA Region 9 Quality Assurance Office's March 17, 2014 approval of the State of California's request to use an Alternate Test Procedure (ATP), authorizing the u e of two concentrations in lieu of the five concentrations plus a control specified in the WET test methods, when using the Test of Significant Toxicity (TST) statistical approach. EPA is withdrawing the approval of the Limited Use ATP, effective immediately, for a number of reason . Please note that at this time, California's Febru ary 12, 2014 ATP request is no longer pending before EPA and hould the State wish to pur ue such an ATP, a new ATP application would be required.

A you may know, the March 17,2014 Limited Use ATP approval was challenged in the U.S. Eastern District Court of California in June 2014 by the Southern California Alliance of Publicly Owned Treatment Works (SCAP) and Central Valley Clean Water Association (CVCWA). *A* a result of the litigation, EPA has become aware of issue related to the State of California's February 12, 2014 reque t as well as EPA Region 9's approval. First, we note that the State's request cited 40 C.F.R. § 136.4, which describes the process for *nationwide* ATP approvals, rather than 40 C.F.R. § 136.5 for a Limited Use ATP. While we continue to believe this was a simple eiTor, we acknowledge that it ha created uncertainty and confusion among the regulated community.

Second, there is cuiTently pending a proposed rulemaking to revise the ATP regulations at 40 C.F.R. Part 136. Plea e see http://water.epa.gov/scitech/methods/cwa/mur2015.cfm. The EPA Administrator signed a proposed rule on February 5, 2015, relevant portion of which are attached. One element of that rulemaking i a proposal to colTect an inadvertent error in the 40 C.F.R. s 136.5 regulatory language regarding Limited U e ATPs. In revising 40 C.F.R. § 136.5 in 2012, EPA had inadvertently included the phrase "or permitting authority" after each instance that the phrase "Regional Alternate Test Procedure Coordinator" or "Regional *A*TP Coordinator" appears in Section 136.5. The effect of this inadvertent inclusion was to authorize State

permitting authorities to approve ATPs. This was not EPA's intention, and EPA has now proposed to delete the phrase "or permitting authority" from Section 136.5. It is EPA's position that the inadvertent error is not implicated in its approval decision here, but plaintiff have raised arguments regarding the phrase "permitting authority" in Section 136.5. To the extent this error has created uncertainty in regards to the appropriateness of the March 17, 2014 ATP approval, EPA believe it is appropriate to withdraw that approval. However, withdrawal of the approval does not affect any aspect of the regulation at 40 C.F.R. Part 136 but concerns only the State's February 12,2014 ATP request.

Third, plaintiff have raised concern with respect to the administrative record for the ATP approval. In light of some of the issues raised by plaintiff, EPA has concluded that it is appropriate to withdraw it ATP approval. If you have any question regarding this action, please contact me at (415) 972-3411.

Sincerely,

Eugenia McNaughton, Ph.D.
Manager, Quality Assurance Office

Cc: Rich Breuer

J. Clarification /Correction to ATP Procedure in 40 CFR 136.4, 136.5 and Allowed Modification in 136.6

40 CFR 136.4 and 136.5 de cribe EPA procedure for obtaining approval to use an altern ate te t procedures either on a national basi , or for limited use by discharger or facilitie specified in the approval. ln the 2012 Method Update Rule, EPA made several clarifying changes to the language of these sections. At the same time, however, in many place in 40 CFR 136.4 and 136.5 where the phra e "Regional Alternate Te t Procedures Coordinator" or "Regional ATP Coordinator" appears, EPA inadvertently also inserted the phrase "o r p rmitting authority" following the phrase. This etTor resulted from the use of the "search and replace" function on the compu ter. The effect of the change was to inadvertently authorize *State* permitting authorities to approve ATP for limited use within the State. EPA nev r intended thi result a is demon trated by two facts. Fir t, in it proposal for the 2012 Update, EPA did not propo e to authorize State PDES permitting authoritie to approve limited u e ATP . econd, the rule state that the approval may be re tricted to specific dischargers or facilities, or to all discharger or facilities "specified in the approvalfor *the Region.*" (empha is added). This language evidence EPA's intent that the Regio n- not the tate – would be authorized to issue any uch limited u e ATP approval. Finally, a further evidence of EPA's intent, in everal place , the te t of the rule make more sen e if read to authorize only the Regional ATP Coordinator, and not the State permitting authority, to approve limited use ATPs. Fore ample, 40 CFR 136.5(d)(1) provide a follows:

> "After a review of the application by the Alternate Te t Proc dure Regional ATP Coordinator or p rmitting authority, the Regional ATP Coordinator or permitting

authority notifies the applicant and the appropriate State agency of approva l or rejection of the u e of the alternate test procedure...."

A curr ntly writt n, if the State i acting on a request for approval, th regulation would r quir the State to inform itself of its own action in approving or rejecting th ATP, a somewhat uperfluou requirement.

Consequently, EPA propose to delete all instances of "or p rmitting authority" from 40 CFR 136.4 and 136.5 to corr ct this error and revi e the rule text to it original intent. Ba ed on thi revision, EPA and EPA alone would have th authority to approv limited u e ATP .

EPA also proposes changes to 40 CFR 136.4 and 136.5 to clarify the process for nationwide approval and the Regional ATP Coordinator's role in limited use ATP approvals. These changes do not significantly change the process, the intent is to make wording simpler and clearer.

Finally, EPA proposes to add language to 40 CFR 136.6(b)(1) to clarify that if a method user is uncertain whether or not a modification is allowed under 40 CFR 136.6, the u er hould contact either its Director or EPA Regional ATP Coordinator.

K. Change to Appendix B to 40 CFR part 136 - Definition and Procedure for the Determination of the MDL

EPA proposes revi ions to the procedu r for determination of the MDL primarily to add r ss laboratory blank contamination and to better account for intra-laboratory variab ility. EPA's consid ration ofrevi ions to th MDL procedure for this rulemaking i pecific to these r vi ion , and oth r chang to the procedure are outside the scope of thi action. The proposed change originated from Th ational Environmental Laboratory Accreditation Confer nee

5. Section 136.4 is amended by revi ing paragraph (a) introductory text, (b), and (c) to read a follow :

§ 136.4 Application for and approval of alternate test procedures for nationwide use.

(a) A written application for review of an alternate te t procedure (alternate method) for nationwide use may be made by letter via email or by hard copy in triplicate to the National Alternate Te t Procedure (ATP) Program Coordinator (National Coordinator), Office of Science and Technology (4303T), Office of Water, U.S. Environmental Protection Agency,200 Pennsylvania Ave. NW, Washington, DC 20460. Any application for an ATP under this paragraph (a) shall:

* * * * *

(b) The National Coordinator may request additional information and analyses from the applicant in order to evaluate whether the alternate test procedure satisfie the appl icabl requirement of thi part.

(c) Approval for nationwide u e.

(1) After a review of the application and any additiona l analy es requested from the applicant, the National Coordinator will notify the applicant, in writing, of whether the ational Coordinator will recommend approval or disapproval of the alt rnate te t procedure for nationwide u e in CWA programs. If the application is not recommended for approval, the National Coordinator may pecify what additional information might lead to a recon ideration of the applicat ion and notify the Regional Alternate Te t Proced ur Coordinator of the di approval recommendation. Ba ed on th National Coordinator's recommended di approval of a propo ed alternate te t proc dure and an a sessment of any current approval for limited use for the

unapproved method, the Regional ATP Coordinator may decide to withdraw approval of the method for limited use in the Region.

(2) Where the National Coordinator has recommended approval of an applicant's request for nationwide use of an alternate test procedure, the ational Coordinator will notify the applicant. The National Coordinator will also notify the Regional ATP Coordinators that they may con ider approval of this alternate te t procedure for limited use in their Regions ba ed on the information and data provided in the application until the alternate test procedure is approved by publication in a final rule in the Federal Register.

(3) EPA will propo e to amend 40 CPR patt 136 to include th alternate te t procedu re in §136.3. EPA hall make available for review all the factual bases for it proposal, including the method, any performance data ubmitted by the applicant and any available EPA analysis of tho e data.

(4) Following public comment, EPA hall publish in the FEDERAL REGISTER a final deci ion on whether to amend 40 CPR part 136 to include the alternate te t proc dure as an approved analytical method for nationwide use.

(5) Whenever the National Coordinator has recommended approval of an applicant's ATP requ st for nationwide use, any per on may request an approval of the method for limited u e under §136.5 from the EPA Region.

6. Section 136.5 is amended by revising paragraphs (a), (b), (c), and (d) to read as follows:

§136.5 Approval of alternate test procedures for limited use.

(a) Any per on may r qu t the Regional ATP Coordinator to approve the u e of an alternate test procedure in th Region.

(b) When the request for the use of an alternate test procedure concerns use in a State with an NPDES permit program approved pursuant to section 402 of the Act, the requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority). The Director will forward the application to the Regional ATP Coordinator with a recommendation for or against approval.

(c) Any application for approval of an alternate test procedure for limited use may be made by letter via email or by hard copy. The application shall include the following:

(1) Provide the name and address of the applicant and the applicable ID number of the existing or pending permit(s) and issuing agency for which use of the alternate test procedure is requested, and the discharge serial number.

* * * * *

(d) Approval for limited use. (1) The Regional ATP Coordinator will review the application and notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. The approval may be restricted to use only with respect to a specific discharge or facility (and its laboratory) or, at the discretion of the Regional ATP Coordinator, to all dischargers or facilities (and their associated laboratories) specified in the approval for the Region. If the application is not approved, the Regional ATP Coordinator shall specify what additional information might lead to a reconsideration of the application.

(2) The Regional ATP Coordinator will forward a copy of every approval and rejection notification to the National Alternate Test Procedure Coordinator.

7. In Section §136.6:

Clean Water Act Methods Update Rule for the Analysis of Effluent

List of Subjects in 40 CFR part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Test procedures, Water pollution control.

Dated:

FEB 0 5 2015

Gina McCarthy, Administrator.